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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,244	09/17/2001	David S. Goldsteen	293/002DIV2	1651
1473	7590	04/27/2004	EXAMINER	
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105				THALER, MICHAEL H
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/955,244	GOLDSTEEN ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 March 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 and 13-27 is/are pending in the application.
 - 4a) Of the above claim(s) 2-11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 13-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

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Claims 2-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 5.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification should be amended to include the feature that the distal portion of the longitudinal structure is sharpened as defined in claim 13.

Claims 1, 13 and 18-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taylor (3,952,742). Taylor discloses elongated guide structure 12 and longitudinal structure 14, a distal portion 14a of the longitudinal structure 12 adapted to penetrate tissue. The elongated guide structure 12 is inherently capable of being insertable into a tubular organ (e.g. an intestine) and extendable along the interior of tubular organ to a point where an aperture may be created through the side wall of the tubular organ which is remote (to some extent) from the location at which the instrument is inserted into the tubular member since elongated guide structure 12 may be 6 inches long (col. 2, lines 37-38). The longitudinal structure

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14 is inherently capable of penetrating the side wall since longitudinal structure 14 is inherently capable of being pushed outwardly through the side wall of the tubular organ where the tubular organ curves to the side while the longitudinal structure 14 remains straight. Alternatively, it would have been obvious that the elongated guide structure 12 is capable of being insertable into a tubular organ (e.g. an intestine) and extendable along the interior of tubular organ since it is so sized. Further, the longitudinal structure 14 is inherently capable of being moved distally relative to guide structure 12 during penetration of the side wall. As to claims 18-27, Taylor discloses balloons 22, 24.

Claims 14, 16 and 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (3,952,742). As to claim 14, Taylor fails to disclose the distal portion of the longitudinal structure 14 as being externally threaded. However, it was well known to provide external threads on surgical devices so that they can more effectively penetrate tissue and be secured thereto. It would have been obvious to include external threads on the Taylor structure 14 so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). As to claim 16,

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Taylor fails to disclose a tubular member disposed about the longitudinal member 14. However, it is old and well known in this art to include a tubular dilator around a penetration member in order to dilate the opening formed by the penetration member. It would have been obvious to include such a tubular dilator around the Taylor longitudinal member 14 so that it too would have this advantage.

Claim 15 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chu et al. (6,176,834). Chu et al., in figure 8, disclose elongated guide structure 14 and longitudinal structure 82, a distal portion of the longitudinal structure 82 adapted to penetrate tissue. The elongated guide structure 14 is inherently capable of being insertable into a tubular organ and extendable along the interior of tubular organ to a point where an aperture may be created through the side wall of the tubular organ which is remote (to some extent) from the location at which the instrument is inserted into the tubular member. The longitudinal structure 82 is inherently capable of penetrating the side wall since longitudinal structure 82 is inherently capable of being pushed outwardly through the side wall of the tubular organ where the tubular organ curves to the side in one direction while the longitudinal structure 82 curves in the

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opposite direction. Alternatively, it would have been obvious that the elongated guide structure 14 is capable of being insertable into a tubular organ and extendable along the interior of tubular organ since it appears to be so sized. The distal portion of the longitudinal structure 82 is resiliently biased to deflect laterally when released from guidance by the guide structure (col. 4, lines 51-59).

Applicant's arguments filed March 9, 2004 have been fully considered but they are not persuasive. Although the Taylor instrument is straight, it is capable of penetrating the side wall of a organ structure where the organ structure is curved.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Specifically, the amendments to claims 18, 21, 24 changed the meanings of "elongated guide structure" and "longitudinal structure". Prior to this amendment, the disclosure indicated that the elongated guide structure was member 250 and the longitudinal structure was member 210 (in view of claims 18, 21 and 24 as originally presented). After this amendment, the disclosure indicates that the elongated guide structure is member 210 and the longitudinal structure is members 220, 230, 240 and 250 (in view of claims 18, 21 and 24 as amended and in view of the amendment to page 16 of the specification). The change of the meanings of "elongated

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guide structure" and "longitudinal structure" brought claims 15-17 within the list of claims that read on the elected species. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone number for the

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organization where this application or proceeding is assigned is
(703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

mht
4/23/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731